In re application:
Kenshi KAMEI et al.
Application No. 10/523,585
Application Filed: October 24, 2003
For: THERAPEUTIC AND/OR PREVENTIVE AGENT FOR DEFECATION DYSFUNCTION

DECLARATION UNDER 37 CFR 1. 132

Honorable Commissioner for Patents
U.S. Patent and Trademark Office
Randolph Building
401 Dulany Street
Alexandria, Virginia 22314

Sir:

I, Kenichi Ozaki, am an inventor of the above-identified application. I am a Japanese citizen, and I hereby declare and state a technical knowledge relating to the subject application.

I declare that I received a graduate degree as Master of Agriculture in March, 1993, from the Graduate School of Tohoku University, and received a Pharmacy Doctorate in March, 2007 , from the Graduate School of Chiba University.

I also declare that I have been employed by Chugai Pharmaceutical Co., Ltd., the Assignee of this application, since 1993 and that I am presently working as a researcher for Fuji Gotemba Research Laboratories of the Assignee, Gotemba-shi, Shizuoka-ken, Japan.

I further declare that I have read the entire contents of the Office Action issued on December 12, 2007 against the above patent application, and that I have read and am familiar with the reference cited in the Office Action by the Examiner.

I declare further that the following statements are true and correct to the best of my knowledge.

I clearly understand that the term "motilin agonists" appearing on page 207, left column, line 16 of Koga et al. refers to erythromycin (EMA), and not to GM-611. It is my expert opinion that the skilled worker or expert would also understand that the paragraph on page 207, left column, lines 14 to 29 in Koga et al. relates to potential therapeutic application of EMA, and not of GM-611.

The migrating motor complex (MMC) is a distinct pattern observed in gastrointestinal tract in the fasting state. The MMC is initiated in stomach triggered by increase of plasma motilin level, and contractions migrate to terminal ileum.

It is generally believed that the MMC does not occur in the digestive state. Koga et al. does not state that the MMC occurs in the digestive state, even administrating motilin agonist (GM-611) (page 269, left column, lines 12 to 30).

Even taking the cited prior art into consideration, to the best of my knowledge, there is no prior art, i.e. no publication as early as the priority date of the present application, which reports that MMC accelerates defecation. On the other hand, it is commonly known that defecation is accelerated by contractions of the colon.

Further, I am unaware of any prior art, providing definitive evidence that any motilin receptor exists in the human colon sufficient to accelerate defecation.

To the best of my knowledge, there is no prior art reporting that an increase of plasma motilin level, which commonly occurs in the fasting state and triggers the initiation of MMC in the stomach, causes any contractions of the colon which would lead to the belief that such an increase of plasma motilin level would accelerate defecation.

I declare further that all statements made herein of my own knowledge are true and that all statements made on the basis of information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patents issued thereon.

May 22, 2008 — Kenichi Ozaki

Date — Kenichi OZAKI